

### **REMARKS**

Claims 28-45 are pending in the present application. Claims 28 and 33 have been amended and support for these claim amendments can be found on page 11, line 21 to page 12, line 3; page 10, lines 6-7; and page 8, lines 12-15.

As an initial matter, Applicants request clarification regarding the identification of the withdrawn claims in this application. In the restriction requirement of October 3, 2003, the Examiner restricted the application to either Group I, drawn to claims 28-39 or Group II, drawn to claims 40-45. The Examiner also issued an election of species requirement if Group II (the method claims) were elected (“upon election of the method[,] applicant is required to elect one of the species below”). Because Applicants elected Group I, drawn to the catheter, Applicants do not believe the species election is applicable and Applicants request clarification on this matter.

Claims 28, 29, 31-32, and 33 stand rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-5 and 15 of U.S. Patent No. 6,319,230 (the ‘230 patent). Claims 28-29 and 31-37 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. Patent No. 5,464,395 to Faxom (“Faxom”). Claims 28-29, 31-37 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. Patent No. 5,419,777 to Hofling (“Hofling”). Claims 28-29 and 31-32 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. Patent No. 4,578,061 to Lemelson (“Lemelson”). Claims 28-29 and 30-31 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by U.S. patent No. 5,728,143 to Gough (“Gough”).

#### **Double Patenting Rejection**

Claims 28 and 33 have been amended to recited that the shaft further comprises “an insert having a lumen extending in a longitudinal direction of the shaft and transitioning to a generally lateral direction adjacent the at least one aperture to direct the at least one secondary member through the at least one aperture.” Claims 1-5 and 15 of the ‘230 patent do not teach or suggest such an insert. As such, Applicants submit that

PATENT  
12013/60402  
09/982,934

the present claims do not claim the same invention as claims 1-5 and 15 of the '230 patent and Applicants request withdrawal of this rejection.

Rejection of Claims Under 35 U.S.C. 102

Applicants submit that none of the references cited against the present claims teach or suggest “a primary penetrating member having a sharpened end,” “at least one secondary member [that] is retractable to a position within [a] primary penetrating member;” or “an insert having a lumen extending in a longitudinal direction of the shaft and transitioning to a generally lateral direction adjacent the aperture to direct the at least one secondary member through the at least one aperture,” as recited in the present claims.

a. Faxom

With respect to Faxom, this reference describes “needle cannulas” with “tissue-piercing tips” that are slidably disposed within the lumen of a catheter. Although multiple needle cannulas are described in Faxom, there is absolutely no description of a second needle cannula that is retractable to a position within a first needle cannula or any other component or portion of the catheter that has a sharpened end. Accordingly, Applicants submit that Faxom does not teach or suggest an “at least one secondary member [that] is retractable to a position within a primary penetrating member,” wherein the “primary penetrating member has a sharpened end,” as recited in the present claims. According to the Examiner, the distal portion or end of the outer catheter of Faxom is considered to be the primary penetrating member. However the distal end of the outer catheter of Faxom does not have a “sharpened end” as explicitly recited in the present claims. Rather, the outer catheter has a “blunt conical nose portion.”

Further, Faxom does not describe an “insert having a lumen extending in a longitudinal direction of the shaft and transitioning to a generally lateral direction adjacent the aperture to direct the at least one secondary member through the at least one aperture.” For at least these reasons, Applicants submit that Faxom does not anticipate the claims and Applicants request withdrawal of this rejection.

b. Hofling

Similarly with respect to Hofling, this reference describes an injection catheter including a catheter tip and a bundle of injection needles. The catheter tip is axially moveable in a sleeve which is connected to a multi-lumen stem having injection needles secured within various lumina. None of the injection needles, however, are retractable within any of the other injection needles or any other component or portion of the catheter that can penetrate tissue and has a "sharpened end," as recited in the present claims. The Examiner refers to element 11 in Hofling as being a "primary penetrating member." However, element 11 refers to the catheter tip which is illustrated in all the drawings as being blunt and is not at all described as being capable of penetrating tissue and having a sharpened end. The only components of the catheter of Hofling that are described as being able to penetrate tissue are the injection needles (see col. 4, lines 66-68). Therefore, Hofling does not teach or suggest an "at least one secondary member [that] is retractable to a position within [a] primary penetrating member," wherein the "primary penetrating member has a sharpened end" as recited in the present claims.

Further, Hofling does not describe an "insert having a lumen extending in a longitudinal direction of the shaft and transitioning to a generally lateral direction adjacent the aperture to direct the at least one secondary member through the at least one aperture." For at least these reasons, Applicants submit that Hofling does not anticipate the claims and Applicants request withdrawal of this rejection.

c. Lemelson

With respect to Lemelson, this reference describes a catheter having a hollow needle moveably supported within the head of the catheter. Similar to the other references described above, Lemelson does not describe the hollow needle being retractable to a position within any component or portion of the catheter that has a sharpened end and can thus be considered a "primary penetrating member," as recited by the present claims. Therefore, Lemelson does not teach or suggest "at least one secondary member [that] is retractable to a position within [a] primary penetrating

member," wherein the "primary penetrating member has a sharpened end" as recited in the present claims.

Further, Lemelson does not describe an "insert having a lumen extending in a longitudinal direction of the shaft and transitioning to a generally lateral direction adjacent the aperture to direct the at least one secondary member through the at least one aperture." For at least these reasons, Applicants submit that Lemelson does not anticipate the claims and Applicants request withdrawal of this rejection.

d. Gough

Lastly, with respect to Gough, this reference describes a multiple antenna ablation apparatus having antennas that can be advanced from a trocar. There is absolutely no description in Gough that these antennas have "sharpened ends," as recited in the present claims. Rather, these antennas are described as delivering electromagnetic energy to tissue mass (see col. 4, lines 58-60) or being used to infuse medium to selected places within the tissue mass (see col. 8, lines 21-31). Such description, however, does not indicate that the antennas have sharpened ends and therefore can be considered "secondary penetrating members," as recited in the present claims. Therefore, Gough does not teach or suggest an "at least one secondary member [that] is retractable to a position within [a] primary penetrating member," as recited in the present claims.

Further, Gough does not describe an "insert having a lumen extending in a longitudinal direction of the shaft and transitioning to a generally lateral direction adjacent the aperture to direct the at least one secondary member through the at least one aperture." For at least these reasons, Applicants submit that Gough does not anticipate the claims and Applicants request withdrawal of this rejection.

**CONCLUSION**

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact

PATENT  
12013/60402  
09/982,934

Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees are required in connection with the filing of this response, such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon's Deposit Account No. 11-0600.

Respectfully submitted,  
KENYON & KENYON

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